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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,045	03/16/2001	Robert E. Scott	D6386/D	7993

7590 06/18/2004

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/811,045	SCOTT, ROBERT E.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10, and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Exhibits A, B, C*.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/09/2004 has been entered. Claim 10, and 12 are amended. Claims 10, and 12 are pending and examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejection and reinstatement of the enablement rejection.

Specification

The disclosure is objected to because of the following informalities: the specification at page 25, line 10 has an incomplete disclosure after "is". Note Exhibit A.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claims 10 and 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention is withdrawn in view of the amendment is withdrawn in view of amendment.

Priority

Applicant's claim for domestic priority to Application NO. 08/801,308, now US Pat. 6,368,790 is acknowledged. However, the application upon which priority is claimed fails to provide adequate support for claim 10 because the proviso statement i.e. excluding subgenera of monoclonal antibodies that binds to SEQ ID NO:1 is not supported by to Application NO. 08/801,308.

Therefore, the effective filing date for instant claim 10 is the filing date of the instant application i.e. 03/16/2001.

Since the priority document, Application No. 08/801,308, now US Pat. 6,368,790 recites antibody "C130" in claim 18, the filing date of instant claim 12 is at least the filing date of Application NO. 08/801,308 i.e. 02/18/1997.

The instant application at page 25 lines 9-10 discloses "The ATCC Accession Number for monoclonal antibody C130 is:" Note the attached Exhibit A (page 25 of the instant application).

Application No. 08/801,308, now US Pat. 6,368,790 discloses "The monoclonal antibody 130 is commercially available from Santa Cruz Biotechnology under the designation PACT (M56). Note Exhibit B (US 6,368,790 columns 9, 10, claims 1-29, total 3 pages).

Applicant at pages 6-8, and 15 of the response filed on 02/09/2004 argues that C130 and M56 are different antibodies, especially at page 15 states that **"C130 was**

not licensed and not commercially available nor has a deposit of the C130 hybridoma has been made." This is a direct contradiction of the statement made in the issued US Pat. Pat. 6,368,790. Note the attached Exhibit B.

Applicant, however, argues that the instant application is a proper divisional application of 08/801,308 and entitled to claim priority to 08/801,308 even though applicant admits that "C130" and M56 are different antibodies, whereas Application NO. 08/801,308, now US Pat. 6,368,790 discloses that "the monoclonal antibody C130 is commercially available from Santa Biotechnology under the designation PACT (M56). Note applicant's own statement quoted in bold above vs. US 6,368,790 columns 10, lines 50-52.

Claim Rejections - 35 USC § 102

Claim 10 remains rejected under 35 U.S.C. 102(b) as being anticipated by either Minoo et al (Nov. 1989, The Journal of Cell Biology, Vol. 109, pages 1937-1946) or Witte et al (1993, Mol. Cell. Differ. Vol. 2, pages 185-195) for the same reasons set forth in the Office action mailed on 9/25/2001.

Claim 10 is drawn to monoclonal antibody capable of binding a protein encoded by SEQ ID NO:2 with the unclear conditional stipulation (note the rejection under 112, Second Paragraph below).

Applicant argues that the amended claim includes a proviso statement excluding antibodies binding **only** within the 1090-1378 segment of the polypeptide of SEQ ID NO:1. Applicant also argues that the instant specification teaches that AC88 and fA12 binds to a specific region within polypeptide, thus, it is proper to exclude these

antibodies in the claim. This argument has been fully considered but found unpersuasive because applicant's argument is not commensurate in scope of claims. The proviso statement does not eliminate only AC88, and FA12 but eliminates subgenus. Further, the specification from bottom of page 11 to page 12 under the heading "P2P cDNA Cloning and Sequencing" discloses that AC88 and FA12 binds to both P2P and hsp90, thus these two antibodies do not **only** binds SEQ ID NO:1 but also binds to hsp90. Claim 10 as currently construed does not exclude the two antibodies AC88 and FA12. Neither the specification nor applicant's response clearly shows where the epitopes lie in instant SEQ ID NO:1 for AC88 or fA12.

Applicant also argues that the amended claim is a composition encompassing more than one monoclonal antibody binding to a specific polypeptide with a known sequence. It is concluded that the claim is not directed to composition but to a genus of monoclonal antibodies, which AC88 and FA12 appear to be two species that belong to said genus capable of binding to the same known sequence (disclosed as SEQ IS NO:1 in the instant specification). Applicant does not provide any data showing where AC88 or fA12 binds in SEQ ID NO:1 or why they are outside of the property boundary of the instantly amended claim 10.

The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the antibodies of the prior art do not bind to instant SEQ ID NO:1 with the unclear proviso statement. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed antibody is different from those taught by the prior art and to establish patentable differences. See

In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

The rejection of Claim 10 under 35 U.S.C. 102(e) as being anticipated by US PAT 5,643,761 (Fisher, issued date of July 1, 1997) is **withdrawn** in view of the new ground of rejection below.

Claim 10 is rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention by Santa Cruz Biotechnology with the antibody catalog number sc-9962, PACT (M56).

Since the instant claim 10 is not supported in Application NO. 08/801,308, now US Pat. 6,368,790, the filing date of instant claim 10 is 03/16/2001.

Claim 10 is drawn to monoclonal antibody that binds to SEQ ID NO:1 with the unclear proviso statement. Since applicant states that C130 and M56 have similar binding characteristics (note the bottom half of page 6, and the paragraph bridging pages 12 and 13 of the Amendment filed on 02/09/2004), and a public use or sale of the invention occurred beginning September 24, 1999, well before the filing date given to the claim 10 (03/16/2001), the antibody with the catalog number sc-9962, PACT (M56) from Santa Cruz Biotechnology is an art 35 U.S.C. 102(b). Note under Priority above for further detail.

The Following are New Grounds for Rejection

Claim Rejections - 35 USC § 112

Claim 10 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 claims a subgenus of monoclonal antibody the limitation "with the proviso that said monoclonal antibody does not bind **only** within a segment of amino acids from amino acid 1090 to amino acid 1378 of said polypeptide having SEQ ID NO:1" but it is not clear what the metes and bounds are for the limitation. Does the limitation excludes a subgenera of monoclonal antibodies binding to an epitope within amino acid 1090 to amino acid 1378 of said polypeptide having SEQ ID NO:1? The word "only" makes the conditional stipulation very confusing as to the property boundary of the claimed invention. If an antibody binds to an epitope within amino acid 1090 to amino acid 1378 of said polypeptide, and also binds to an epitope within amino acid of 1-1000 due to a three-dimensional folding of SEQ ID NO:1 protein, or another structurally similar protein, does that antibody also excluded within property boundaries of the claimed invention?

Claim 12 recites "C130", but it is not clear what the metes and bounds. C130 is a lab designated name for a specific antibody. Reciting deposit number for C130 of an acceptable depository would obviate this rejection.

The rejection of **claim 12** set forth in the Office action mailed on 09/25/2002 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **reinstated** based on applicant's argument at page 13 of the response filed on 02/09/2004. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is noted that applicant at page 5 and 6 of the Response filed on 11/05/2002 (note the attached Exhibit C) argued that C130 was available from Santa Cruz Biotechnology.

However, applicant now argues for traversing the art rejection of record (note page 13, first paragraph of the response filed on 02/09/2004) **that C130 was not licensed, and not commercially available, nor had a deposit of the C130 hybridoma has been made**. Therefore, the enablement rejection is reinstated.

Claim 12 recites a monoclonal antibody C130. It is apparent that the hybridoma secreting the antibody C130 is required to practice the claimed invention. As required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the hybridoma that produces the antibody C130 in claim 12. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the hybridoma secreting antibody C130, and it does not appear to be readily available

material. Deposit of the hybridoma would satisfy the enablement requirements of 35 U.S.C. 112.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Claims 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

This new matter rejection is made because of the newly added proviso statement i.e. "with the proviso that said monoclonal antibody does not bind only within a segment of amino acids from amino acid 1090 to amino acid 1378 of said polypeptide having SEQ ID NO:1." The specification and the claims as originally filed do not exclude the newly claimed subgenera of the monoclonal antibodies. Further, the specification and the claims as originally filed do not have support for a region of amino acids 1090 to 1378 of SEQ ID NO:1.

Claim Rejections - 35 USC § 102

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by US PAT 5,643,761 (Fisher, issued date of July 1, 1997, a copy provided in the Office action mailed on 09/25/2002).

Since the instant claim 10 is not supported in Application NO. 08/801,308, now US Pat. 6,368,790, the filing date of instant claim 10 is 03/16/2001.

Claim 10 is drawn to monoclonal antibodies with the unclear proviso statement. See above rejection of claim 10 under 112, Second Paragraph for further detail about the unclear proviso statement.

US PAT 5,643,761 teaches in Figure 14 and column 4 lines 44-51 antibody binds to P2P.

The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that antibody of the prior art do not bind to the C-terminal half of the protein in Figure 2. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed antibody is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Applicant has not provided any objective evidence how the instantly claimed monoclonal antibody is different from the monoclonal antibody disclosed in Fisher.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina C Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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